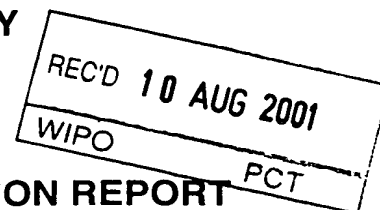


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference REP06103WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/01290	International filing date (day/month/year) 06/04/2000	Priority date (day/month/year) 06/04/1999
International Patent Classification (IPC) or national classification and IPC C12Q1/68		
Applicant MEDICAL BIOSYSTEMS LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.


☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

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3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 26/10/2000	Date of completion of this report 07.08.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer BROCHADO GARGANTA, M Telephone No. +49 89 2399 8935



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01290

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-8 as originally filed

Claims, No.:

1-6 as originally filed

Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/01290

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-5
	No:	Claims	6
Inventive step (IS)	Yes:	Claims	1-5
	No:	Claims	6
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/01290

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

(A) SUTTON MARK D ET AL: 'Escherichia coli DnaA protein: The N-terminal domain and loading of DnaB helicase at the E. coli chromosomal origin.' JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 273, no. 51, 18 December 1998 (1998-12-18), pages 34255-34262, XP002171544 ISSN: 0021-9258

(B) WO 99 05315 A (DENSAM DANIEL HENRY ;MEDICAL BIOSYSTEMS LTD (GB)) 4 February 1999 (1999-02-04)

2. Novelty

2.1 The subject-matter of claim 1, relating to a method for sequencing a polynucleotide, wherein a target polynucleotide is reacted with a helicase/primase enzyme and the interaction between the enzyme and a nucleotide on the target is detected, is new in the sense of Article 33(2) PCT, because such a method is not disclosed in the prior art.

The same applies to dependent claims 2-5. Therefore these claims are also novel (Article 33(2) PCT).

2.2 The subject-matter of claim 6, relating to a sensor chip comprising a helicase/primase enzyme immobilised thereon, is not new in the sense of article 33(2) PCT, because this subject-matter is already known from document A.

Document A discloses a method for analysing protein-protein interactions, wherein the **helicase is immobilised on a biosensor (spr)** (see Abstract and page 34256, column 1).

**INTERNATIONAL PRELIMINARY
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International application No. PCT/GB00/01290

3. Inventive step

- 3.1 Document A describes the use of the biosensor with immobilised helicase for the analysis of protein-protein interactions. There is no reference to the possibility of using it for sequencing nucleic acids.

Document B discloses a sequencing method using immobilised polymerase, wherein the incorporation of mononucleotides is detected by surface plasmon resonance (see Abstract). No reference is made to helicase.

Thus, it would not be obvious for the skilled person to combine the features set out in documents A and B and arrive in this way to the subject-matter of claim 1. Therefore, claims 1-5 are considered to be inventive as required by Article 33(3) PCT.

Re Item VI

Certain documents cited

Document WO 01 25480 A is an earlier document, but was published on or after the international filing date. If the application enters the regional phase, this document could be relevant to the question of novelty, pursuant to Article 54(3) and (4) EPC, insofar as the same Contracting State/s would be designated, if the date of priority is not validly claimed for the relevant parts of the present application.